

CLAIMS

1. A purified expressed δ tryptase polypeptide or fragment or analogue thereof.
2. The polypeptide as claimed in claim 1, wherein the polypeptide is the human δ tryptase polypeptide.
- 5 3. The polypeptide as claimed in claim 2, wherein the polypeptide comprises:
 - (a) the amino acid sequence as set forth in SEQ ID NO:1 or SEQ ID NO:2; or
 - (b) the amino acid sequence as set forth in SEQ ID NO:1 or SEQ ID NO:2 including one or more conservative amino acid substitutions.
- 10 4. A purified, expressed polypeptide wherein said polypeptide is a variant of the polypeptide as claimed in any one of the preceding claims.
5. The polypeptide of claim 4, wherein the variant polypeptide is generated by alternative splicing of the primary RNA transcript encoding the polypeptide as claimed in any one of claims 1 to 3.
- 15 6. The polypeptide of claim 4 or 5 wherein the variant polypeptide comprises:
 - (a) the amino acid sequence as set forth in SEQ ID NO:3; or
 - (b) the amino acid sequence as set forth in SEQ ID NO:3 including one or more conservative amino acid substitutions.
7. A recombinant host cell expressing the polypeptide as claimed in any one of the preceding claims.
- 20 8. An antibody that selectively binds to the polypeptide as claimed in any one of claims 1 to 6.
9. A method of identifying a compound that interacts with the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6, the method comprising the steps of:
 - 25 (a) contacting a candidate compound with the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6 under conditions suitable to enable interaction of the candidate compound to the polypeptide or fragment or analogue thereof; and
 - (b) assaying for activity of the polypeptide or fragment or analogue thereof.
- 30 10. The method of claim 9 wherein assaying for activity of the polypeptide or fragment or analogue thereof comprises adding a labelled substrate and measuring a change in the labelled substrate.

11. A method of identifying a compound that binds to the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6, the method comprising the steps of:

(a) contacting a candidate compound with the polypeptide or fragment or analogue thereof of any one of claims 1 to 6; and

5 (b) assaying for the formation of a complex between the candidate compound and the polypeptide or fragment or analogue thereof.

12. A method of screening for a compound that modulates the activity of the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6, the method comprising the steps of:

10 (a) contacting the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6 with a candidate compound under conditions suitable to enable interaction of the candidate compound to the polypeptide or fragment or analogue thereof; and

(b) assaying for activity of the polypeptide or fragment or analogue thereof.

13. The method of claim 12 wherein assaying for activity of the polypeptide or fragment or analogue thereof comprises adding a labelled substrate and measuring a change in the labelled substrate.

14. The method of claim 12 or 13 wherein the modulation of activity is an inhibition of activity of the polypeptide or fragment or analogue thereof.

15. A method of diagnosing a disease state, or predisposition to a disease state, in a subject, the method comprising the steps of:

(a) isolating a biological sample from the subject; and

20 (b) assaying for expression of the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6 in the sample.

16. The method of claim 15 wherein assaying for the expression of the polypeptide or fragment or analogue thereof comprises contacting the biological sample with a compound capable of interacting with the polypeptide such that the interaction can be detected.

17. The method of claim 16 wherein the compound capable of interacting with the polypeptide or fragment or analogue thereof is an anti- δ tryptase antibody.

18. The method of any one of claims 15 to 17 wherein the disease state is an inflammatory disease.

19. The method of claim 18 wherein the inflammatory disease is a mast cell-associated inflammatory disease.

20. The method of claim 19 wherein the inflammatory disease is selected from the group consisting of: asthma, allergic rhinitis, urticaria, angioedema, eczematous anaphylaxis, dermatitis such as atopic dermatitis, hyperproliferative skin disease, peptic ulcers, inflammatory bowel disorder, ocular and vernal conjunctivitis, rheumatoid arthritis, and inflammatory skin conditions.

5 21. A method of identifying an agent which is an inhibitor of mast cell-mediated inflammation, the method comprising contacting a cell or cell extract with the agent, determining whether there is a change in the activity of a δ tryptase polypeptide or fragment or analogue thereof, and thereby determining whether the agent is an inhibitor of mast cell-mediated inflammation.

10 22. The method of claim 21 wherein activity of the polypeptide or fragment or analogue thereof is determined by adding a labelled substrate and measuring a change in the labelled substrate.

23. The method of claim 21 or 22 wherein the agent binds to the δ tryptase polypeptide or fragment or analogue thereof.

15 24. A method of identifying an agent suitable for use in the treatment or prevention of a mast cell-mediated inflammatory disease state in a subject, the method comprising isolating a biological sample from the subject, contacting the sample with a candidate agent, determining whether there is a change in the activity of a δ tryptase polypeptide or fragment or analogue thereof in the sample, and thereby determining whether the agent is suitable for use in the treatment of the
20 disease state.

25. The method of claim 24 wherein the inflammatory disease is selected from the group consisting of: asthma, allergic rhinitis, urticaria, angioedema, eczematous anaphylaxis, dermatitis such as atopic dermatitis, hyperproliferative skin disease, peptic ulcers, inflammatory bowel disorder, ocular and vernal conjunctivitis, rheumatoid arthritis, and inflammatory skin conditions.

25 26. A method for treating or preventing a disease state in a subject, the method comprising administering to the subject a therapeutically effective amount of a compound identified by the method of any one of claims 9 to 14 or an agent identified by the method of any one of claims 21 to 25.

27. The method of claim 26 wherein the disease state is an inflammatory disease.

30 28. The method of claim 27 wherein the inflammatory disease is a mast cell-associated disease.

29. The method of claim 27 wherein the inflammatory disease is selected from the group consisting of: asthma, allergic rhinitis, urticaria, angioedema, eczematous anaphylaxis, dermatitis such as atopic dermatitis, hyperproliferative skin disease, peptic ulcers, inflammatory bowel disorder, ocular and vernal conjunctivitis, rheumatoid arthritis, and inflammatory skin conditions.

5 30. A method of inhibiting mast cell-mediated inflammation in a subject, the method comprising administering to the subject a therapeutically effective amount of an agent identified by the method of any one of claims 21 to 25 or a compound identified by the method of any one of claims 9 to 14.

10 31. A kit for use in identifying a compound that interacts with or binds to the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6, wherein said kit comprises at least one antibody as claimed in claim 8 and/or at least one polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6.

15 32. A kit for use in screening for a compound that modulates the activity of the polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6, wherein said kit comprises at least one antibody as claimed in claim 8 and/or at least one polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6.

33. A kit for use in diagnosing a disease state, or predisposition to a disease state, in a subject, wherein said kit comprises at least one antibody as claimed in claim 8 and/or at least one polypeptide or fragment or analogue thereof as claimed in any one of claims 1 to 6.